

Special 510(k) Premarket Notification
 GE Medical Systems - LOGIQ 100 PRO Ultrasound System
 August 7, 2001

AUG 23 2001

Attachment B:
Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).



GE Medical Systems

*General Electric Company
 P.O. Box 414, Milwaukee, WI 53201*

Section a):

1. Submitter: GE Medical Systems
 PO Box 414
 Milwaukee, WI 53201

Contact Person: Allen Schuh,
 Manager, Safety and Regulatory Engineering
 Telephone: 414-647-4385; Fax: 414-647-4090

Date Prepared: August 7, 2001
2. Device Name: GE LOGIQ 100 PRO Diagnostic Ultrasound System
 Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
3. Marketed Device: GE LOGIQ α 100 diagnostic ultrasound system: K953752, currently in commercial distribution.
4. Device Description: The GE LOGIQ 100 PRO is a portable general purpose diagnostic ultrasound system. It consists of a small hand-carried console, weighing approximately 22 lbs., providing real-time B and M-mode images with a variety of linear and curved-linear array type transducers. The user interface includes a fold down keyboard, specialized controls and a B&W video CRT display.
5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Cardiac (adult & pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional; Transrectal (TR); and Transvaginal (TV) applications.
6. Comparison with Predicate Device: The GE LOGIQ 100 PRO is of a comparable type and substantially equivalent to the current GE LOGIQ α 100. It has the same technological characteristics, is comparable in key safety and effectiveness features, it utilizes similar design, construction, and materials, and has the same intended uses and basic operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
2. Clinical Tests: None required.
3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE LOGIQ 100 PRO Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 23 2001

Mr. Allen Schuh
Manager, GE Ultrasound Safety
and Regulatory Engineering
GE Medical Systems
General Electric Company
P.O. Box 414
MILWAUKEE WI 53201

Re: K012560
Trade Name: GE LOGIQ 100 PRO Diagnostic Ultrasound System
Regulatory Class: II/21 CFR 892.1560
Product Code: 90 IYO
Dated: August 7, 2001
Received: August 8, 2001

Dear Mr. Schuh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ 100 PRO Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C36
C55
E72
L76
C31
VE5
CZB
LB

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

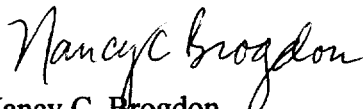
This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97).

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

A handwritten signature in black ink that reads "Nancy C. Brogdon". The signature is written in a cursive style with a large, stylized 'N' and 'B'.

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 100 PRO Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P						P			
Abdominal ^[1]	P	P						P			
Pediatric	P	P						P			
Small Organ ^[2]	P	P						P			
Neonatal Cephalic	P	P						P			
Adult Cephalic											
Cardiac ^[3]	P	P						P			
Peripheral Vascular	P	P						P			
Musculo-skeletal Conventional	P	P						P			
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P	P						P			
Transvaginal	P	P						P			
Transurethral											
Intraoperative ^[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Urology/Prostate

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[*] Combined mode is B/M.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number R012560

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 100 PRO with C36 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P						P			
Abdominal ^[1]	P	P						P			
Pediatric	P	P						P			
Small Organ (specify) ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]	P	P						P			
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN;

[3] Cardiac is adult and pediatric;

[*] Combined mode is B/M.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Maney Broadon
 (Division Sign-off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K012560

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ 100 PRO with C55 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P						P			
Abdominal ^[1]	P	P						P			
Pediatric	P	P						P			
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

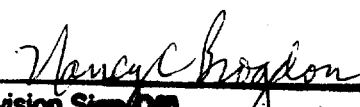
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Urology;

[*] Combined mode is B/M.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K012560

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 100 PRO with E72 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	E						E			
Abdominal ^[1]	P	E						E			
Pediatric	P	E						E			
Small Organ (specify)											
Neonatal Cephalic	P										
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P						P			
Transvaginal	P	P						P			
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Urology/Prostate;

[*] Combined mode is B/M.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Higgins
 (Division Sign-off)
 Division of Regulatory, Abdominal,
 and Radiological Devices
 510(k) Number K012560

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ 100 PRO with L76 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	E	E						E			
Abdominal ^[1]	P	P						P			
Pediatric	P	P						P			
Small Organ ^[2]	P	P						P			
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P						P			
Musculo-skeletal Conventional	P	P						P			
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Urology;

[2] Small organ includes breast, testes, thyroid.

[*] Combined mode is B/M.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number 14012560

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ 100 PRO with C31 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	E	E						E			
Abdominal	E	E						E			
Pediatric	E	E						E			
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]	E	E						E			
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [*] Combined mode is B/M;

[3] Cardiac is Adult and Pediatric

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number 16019560

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ 100 PRO with VE5 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	E	E						E			
Pediatric	E	E						E			
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN;

[*] Combined mode is B/M.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

Nancy C Brogdon
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number 1-K010560

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ 100 PRO with CZB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics											
Abdominal	E	E						E			
Pediatric	E	E						E			
Small Organ ^[2]	E	E						E			
Neonatal Cephalic	E	E						E			
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5] (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											


N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [2] Small organ includes breast, testes, thyroid.

[*] Combined mode is B/M..

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010560

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ 100 PRO with LB Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	E	E						E			
Abdominal ^[1]	E	E						E			
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	E	E						E			
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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[*] Combined mode is B/M.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K012560